Pfenex Reports First Quarter 2020 Results and Provides Business Update

SAN DIEGO, May 7, 2020 — Pfenex Inc. (NYSE American: PFNX) is a development and licensing biotechnology company focused on leveraging its proprietary protein production platform, Pfenex Expression Technology®, to develop next generation and novel protein therapeutics to meaningfully improve existing therapies and create novel therapies for some of the biological targets linked to critical diseases still waiting to successfully be addressed. Pfenex has developed a pipeline that is diversified across multiple assets, including a U.S. Food and Drug Administration (FDA)-approved PF708 product indicated for the treatment of osteoporosis in certain patients at high risk for fracture, and novel and next generation therapeutic product candidates. Today Pfenex Inc. reported financial results for the first quarter ended March 31, 2020 and provided a business update.

"We believe this is an exciting time for Pfenex as we continue to work toward opportunities and potential milestones for our three lead programs: PF708, including the FDA-approved PF708 product, our collaboration with Jazz Pharmaceuticals to develop PF743 (JZP-458) and PF745 (JZP-341), as well as our CRM197 based collaborations," stated Eef Schimmelpennink, Chief Executive Officer of Pfenex. "We believe one of the opportunities for our success is PF708, approved by the FDA late last year, which is a proposed therapeutic equivalent to Forteo® (teriparatide injection). Recently, we announced that the FDA notified Alvogen, our commercialization partner for PF708, via a general advice letter that additional comparative use human factors data, specifically from Forteo experienced users, would be required before a therapeutic equivalence rating relative to Forteo could be determined. While a disappointing delay to the planned timeline for our commercialization strategy for PF708, we are pleased the FDA's therapeutic equivalence evaluation is continuing and that the FDA's feedback provides guidance for what is needed to achieve an "A" therapeutic equivalence designation. With the aim to confirm our understanding of the items outlined in the general advice letter, Alvogen has begun discussing next steps with the FDA, and plans on submitting additional supportive information, as well as clarifying questions in the near future."

"We are also pleased to see that both Jazz and Merck continue to indicate that they are working towards submitting their biologics license applications (BLAs) for JZP-458 and V114, respectively," Mr. Schimmelpennink continued. "As our three lead programs have advanced over the last two years, we believe the underlying value of our patented Pfenex Expression Technology platform has also been recognized. We have started to evaluate new opportunities and recently expanded our pipeline to include development of our wholly owned peptide product candidate, PF810, and the Arcellx cell therapy collaboration with PF753 and PF754. We are pleased with the early progress these programs have already shown, which lays the foundation for our extension into the development of novel biopharmaceutical products. Our first biopharmaceutical candidate is currently being expressed for lead selection and optimization in the Pfenex platform. In looking at our strategy, we believe we now have three well-formed pillars to our development strategy," concluded Mr. Schimmelpennink.

COVID-19 Update

As the COVID-19 pandemic has developed, we have taken numerous steps to help ensure the health and safety of our employees and their families. We are maintaining social distancing and enhanced cleaning protocols and usage of personal protective equipment, where appropriate. Since the stay at home order was put in place in the state of California, the volume of ongoing lab work has been reduced, and only critical program work in the lab has continued with staggered lab employee work shifts to minimize risk of exposure to COVID-19, which has and may continue to disrupt or delay our ability to conduct clinical and preclinical research activities. Employees whose tasks can be performed offsite have been instructed to work from home. We are continuing to monitor any impacts to our business or our programs related to the pandemic.

Business Review and Update

PF708 product and proposed therapeutic equivalent to Forteo

Pfenex and Alvogen are in the process of seeking FDA designation of PF708 as therapeutically equivalent to Forteo which, if achieved, may permit PF708 to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states in the United States. The therapeutic equivalence rating for this product will be primarily based on the FDA evaluating three distinct requirements that center around showing pharmaceutical equivalence, bioequivalence and human factors comparability. On April 14, 2020, Pfenex announced that the FDA informed Alvogen, via a general advice letter, that additional comparative use human factors data, specifically from Forteo experienced users, would be required before the FDA could make a determination regarding the therapeutic equivalence of the FDA-approved PF708 product relative to Forteo. The FDA also provided feedback on study

methodology to generate this additional comparative use human factors data. Pfenex plans to work closely with Alvogen and the FDA to generate and submit these additional data as soon as possible.

In the fourth quarter of 2019, the FDA approved the new drug application (NDA) for PF708, which was submitted under the 505(b)(2) regulatory pathway, with Forteo (teriparatide injection) as the reference drug. Like Forteo, the FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk for fracture. If PF708 is designated as therapeutically equivalent to Forteo, Pfenex will be eligible to receive up to an additional $15 million in support and regulatory milestone payments from Alvogen, which is subject to reduction over time, and may also be eligible to receive from Alvogen up to a 50% gross profit split on U.S. sales of PF708 from Alvogen. If rated differently, the Company will be eligible to receive from Alvogen up to a 40% gross profit split on sales.

Upon PF708 FDA approval in October 2019, we transferred responsibility to Alvogen for all of the commercial manufacturing, supply chain management, and commercialization costs. Alvogen is well advanced with its commercial strategy planning in the U.S., which includes evaluating a potential launch ahead of or upon an FDA decision on therapeutic equivalence. This preparation has included negotiations with the payers in the U.S., including Medicare Part D plans and private payers. In support of these negotiations during the first quarter, Alvogen published the wholesale acquisition cost for the FDA approved PF708 product.

Alvogen, which also has exclusive development and commercialization rights for PF708 in the European Union (EU), Middle East and North Africa (MENA) and the Rest-of-World territories (except those licensed to China NT Pharma Group Company Limited (NT Pharma) and, when assigned, Beijing Kangchen Biological Technology Co., Ltd. (Kangchen), as further discussed below) currently has exclusive commercialization agreements for PF708 with Theramex in Europe and Switzerland, PharmBio Korea in South Korea, JAMP Pharma in Canada, Kamada Ltd. in Israel and Juno Pharmaceutical Pty. Ltd. in Australia and New Zealand. In the EU, the accepted Marketing Authorization Application (MAA) for PF708 is under review by the European Medicines Agency (EMA) and continues to make progress. Pfenex believes PF708 could receive regulatory approval as early as the second half of 2020, subject to granting of a marketing authorization by the European Commission under the EU centralized procedure and other factors. If approved, PF708 would receive marketing authorization in all member states of the EU, as well as in Iceland, Liechtenstein and Norway, and be commercialized by Alvogen's partner Theramex. The MAA for PF708 was submitted by Alvogen to the EMA as a biosimilar to Forsteo®, which achieved $253 million in sales in the E.U. in 2019. Alvogen has also submitted a MAA to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA), and under the terms of its exclusive commercialization agreements, Alvogen will be responsible for the local activities in South Korea, Canada and in Australia and New Zealand through PharmBio, JAMP Pharma, and Juno Pharmaceuticals Pty Ltd., respectively. Alvogen is currently working on licensing agreements for additional territories.

In addition, on April 18, 2018 Pfenex signed a Development and License Agreement granting an exclusive license to NT Pharma to commercialize PF708, upon receipt of applicable marketing authorizations, in Mainland China, Hong Kong, Singapore, Malaysia and Thailand and a non-exclusive license to conduct development activities in such territories with respect to PF708. On April 21, 2020, Pfenex entered into a Deed of Assignment and Amendment (Deed) with NT Pharma, NT Pharma International Company Limited (NT International), and Kangchen, a wholly-owned subsidiary of Beijing Konruns Pharmaceutical Co., Ltd (Konruns). Pursuant to the Deed, Pfenex agreed to allow NT Pharma to assign its rights and obligations to Kangchen. Accordingly, all of NT Pharma's rights under the Development and License Agreement will be assigned to Kangchen, and Kangchen will assume all of NT Pharma's obligations under the Agreement. In a related transaction, NT Pharma, through NT International, will obtain an equity interest in Kangchen and each of NT Pharma and Konruns, as the ultimate parents of Kangchen, will jointly and severally guarantee for the benefit of Pfenex the obligations of Kangchen under the Development and License Agreement.

Pfenex believes the FDA-approved PF708 product and PF708, upon approval for marketing in other countries, have the potential to enhance patient access to an important therapy as a cost-effective alternative to Forteo, which had $1.4 billion in global sales in 2019.

Jazz Collaboration Agreement

Pfenex has a development and license agreement with Jazz Pharmaceuticals plc (Jazz) for two products: PF743 (JZP-458), a recombinant Erwinia asparaginase, and PF745 (JZP-341), a long-acting recombinant Erwinia asparaginase. Jazz is currently conducting a pivotal Phase 2/3 clinical study for JZP-458 in collaboration with Children's Oncology Group and enrollment is ongoing. Jazz indicated on its recent quarterly conference call that it has received fast track designation for PF743 and that it is continuing to work toward their goal of BLA submission as early as the fourth quarter of this year.

Under the terms of the development and license agreement, Pfenex is eligible to receive an aggregate total of up to $224.5 million in development and sales milestone fees, of which $162.5 million is still eligible to be received. This includes up to $3.5 million for development milestones, $34 million in regulatory milestones and $125 million in sales milestones. Pfenex may also be eligible to receive tiered mid-single digit royalties based on worldwide sales of any products resulting from the collaboration.

CRM197

CRM197 is a non-toxic mutant of diphtheria toxin. It is a well characterized protein and functions as a carrier for polysaccharides and haptens, making them immunogenic. CRM197 is currently being used by Pfenex's vaccine development focused pharmaceutical partners, including in multiple Phase 3 clinical studies by Merck & Co., Inc. (Merck) and the Serum Institute of India Private Ltd. (SIIPL) for such diseases as pneumococcal and meningitis bacterial infections.

Merck is using Pfenex's CRM197 in its vaccines including V114, an investigational 15-valent polyvalent conjugate vaccine for the prevention of pneumococcal disease, currently in 15 Phase 3 clinical studies. If approved, V114 is expected to be positioned as a key product in the pneumococcal vaccine market.

SIIPL is using Pfenex's CRM197 in multiple programs including the 10-valent pneumococcal vaccine, Pneumosil®, and a pentavalent meningococcal conjugate vaccine (A, C, Y, W-135, X) which is currently in a Phase 3 clinical trial. Pneumosil achieved WHO prequalification in the fourth quarter of 2019 and SIIPL is preparing to make the product available for procurement by United Nations agencies and the GAVI vaccine alliance. SIIPL is also completing a phase 3 clinical trial for Pneumosil that will support a regulatory submission in India. Pfenex is eligible to receive a tiered royalty payment based upon net sales for both products, subject to regulatory approval.

Arcellx - sparX Protein Development Agreement

In the fourth quarter of 2019 and first quarter of 2020, Pfenex completed the development and transfer of sparX 1 (PF753) and sparX 2 (PF754), respectively, under its development, evaluation and license agreement with Arcellx. This agreement provides access to the Pfenex Expression Technology platform to advance Arcellx's proprietary sparX proteins that activate, silence and reprogram antigen-receptor complex T cell-based therapies. Arcellx has opted into the commercial license for both production strains. Under the terms of the agreement, Pfenex is eligible to receive development funding in addition to development, regulatory and commercial milestones ranging from $2.6 million to $18 million for each product incorporating a sparX protein expressed using the Pfēnex Expression Technology, as well as royalties on worldwide sales of any such products.

Financial Highlights for the First Quarter 2020

Total Revenue decreased by $7.2 million, or 91%, to $0.7 million in the three-month period ended March 31, 2020, compared to $7.9 million in the same period in 2019. The decrease in revenue was primarily due to significant milestone and upfront payments from Alvogen in the first quarter of last year, attributable to FDA acceptance of our NDA for PF708 and the granting of licenses for additional geographic areas for PF708. In addition, revenue related to our Jazz collaboration agreement was earned in the first half of 2019, work continued to scale back on our Px563L product candidate under our government contract with BARDA, and sales of our CRM197 product tend to fluctuate quarter by quarter.

Cost of Revenue decreased by approximately $1.3 million, or 78%, to $0.3 million in the three-month period ended March 31, 2020, compared to $1.6 million in the same period in 2019. The decrease was primarily due to a decrease in sales of our CRM197 product in the quarter and declining activity related to the BARDA contract.

Research and development expenses decreased by approximately $2.1 million, or 26%, to $5.8 million in the three-month period ended March 31, 2020, compared to $7.9 million in same period in 2019. The decrease was primarily due to timing of expenses related to our lead product candidate PF708. Significant activity occurred leading up to and shortly after submission of the NDA to the FDA, which occurred in December 2018.

Selling, general and administrative expenses increased by approximately $0.2 million, or 4%, to $4.7 million in the three-month period ended March 31, 2020, compared to $4.5 million in the same period in 2019. The increase was primarily due to legal and consulting fees.

Cash and cash equivalents as of March 31, 2020, were $65.6 million, which includes net proceeds of $19.4 million from the sale of shares of common stock through an "at the market" equity offering. Pfenex believes that its existing cash and cash equivalents and cash inflow from operations will be sufficient to meet its anticipated cash needs for at least the next 12 months.

Conference Call Information

The Pfenex management will host a conference call and webcast today at 4:30 PM Eastern Time. Participants may access the call by dialing 888-220-8451 (Domestic) or 856-344-9221 (International), the conference ID number is: 3922891. The call will also be

webcast and can be accessed from the Investors section of the Company's website at www.pfenex.com or http://public.viavid.com/index.php?id=139459.

A replay of the call will also be available through May 14th. Participants may access the replay from the Investors section of the Company's website at www.pfenex.com or http://public.viavid.com/index.php?id=139459.

About PF708

PF708 was approved in the U.S. under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. The FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk for fracture. Pursuant to the Development and License Agreement with Alvogen, Pfenex has transferred the NDA for the FDA-approved PF708 product, and Alvogen is responsible for manufacturing and commercializing the product in the U.S. and for fulfilling all regulatory requirements associated with maintaining the PF708 NDA. Alvogen also has exclusive rights to commercialize and manufacture PF708 in the EU, certain countries in MENA, and the Rest of World (ROW) territories (the latter defined as all countries outside of the EU, U.S. and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). A marketing authorization application for PF708 has been filed and accepted with the EMA using the biosimilar pathway with Forsteo® as the reference medicinal product and has been filed with the Kingdom of Saudi Arabia's SFDA. Pursuant to the Development and License Agreement with China NT Pharma Group Company Limited (NT Pharma) we granted an exclusive license to NT Pharma to commercialize PF708 in Mainland China, Hong Kong, Singapore, Malaysia and Thailand and a non-exclusive license to conduct development activities in such territories with respect to PF708. In April 2020, we entered into a Deed of Assignment and Amendment (Deed) with NT Pharma, NT Pharma International Company Limited, and Beijing Kangchen Biological Technology Co., Ltd. (Kangchen), a wholly-owned subsidiary of Beijing Konruns Pharmaceutical Co., Ltd (Konruns). Pursuant to the Deed, we agreed to allow NT Pharma to assign its rights and obligations under the Development and License Agreement with us to Kangchen. Accordingly, all of NT Pharma's rights under the Development and License Agreement will be assigned to Kangchen, and Kangchen will assume all of NT Pharma's obligations under the Agreement. Forteo® and Forsteo® are approved and marketed by Eli Lilly companies for the treatment of osteoporosis in certain patients with a high risk for fracture. Forteo® and Forsteo® achieved $1.4 billion in global product sales in 2019.

About Pfenex Inc.

Pfenex is a development and licensing biotechnology company focused on leveraging its proprietary protein production platform, Pfenex Expression Technology®, to develop next generation and novel protein therapeutics to meaningfully improve existing therapies and create novel therapies for some of the biological targets linked to critical diseases still waiting to successfully be addressed. Using the patented Pfenex Expression Technology platform, Pfenex has created a broad pipeline that is diversified across multiple assets, including U.S. Food and Drug Administration (FDA) approved, next generation and novel biopharmaceutical products. Pfenex's lead product candidate is PF708, a therapeutic equivalent candidate to Forteo® (teriparatide injection). PF708 has been approved in the U.S. for the treatment of osteoporosis in certain patients at high risk for fracture, and marketing authorization applications are pending in other jurisdictions. In addition, Pfenex is developing hematologic oncology products in collaboration with Jazz Pharmaceuticals, including PF743, a recombinant *Erwinia* asparaginase, and PF745, a half-life extended recombinant *Erwinia* asparaginase. Pfenex also uses its Pfenex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein for use in prophylactic and therapeutic vaccines.

Pfenex investors and others should note that Pfenex announces material information to the public about Pfenex through a variety of means, including its website (http://www.pfenex.com/), its investor relations website (http://pfenex.investorroom.com/), press releases, SEC filings, public conference calls, corporate Twitter account (https://twitter.com/pfenex), Facebook page (https://www.facebook.com/Pfenex-Inc-105908276167776/timeline/), and LinkedIn page (https://www.linkedin.com/company/pfenex-inc) in order to achieve broad, non-exclusionary distribution of information to the public and to comply with its disclosure obligations under Regulation FD. Pfenex encourages its investors and others to monitor and review the information Pfenex makes public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.

Cautionary Note Regarding Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Pfenex's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern Pfenex's future expectations, strategy, plans or intentions. Forward-looking statements in this press release include, but are not limited to, statements regarding the future potential of Pfenex's product candidates and the company in general, including future plans to advance, develop, manufacture and commercialize its product candidates; the timing of the potential commercial launch of its products.; Pfenex's expectations with respect to the sufficiency of its cash resources; regulatory developments, including expectations to submit additional human factors data to FDA, expectations with respect to a comparative use human factor study that addresses the FDA's views, and the potential timing of marketing authorization

in the E.U. for PF708; potential market opportunities for PF708 and Pfenex's other product candidates, including the benefits of use of such products; Pfenex's expectations regarding the timing and advancement of clinical trials and studies and the types of future clinical trials and studies for its product candidates and product candidates under the Jazz collaboration; Pfenex's expectations with regard to future milestones, royalty payments, and reimbursements from Pfenex's collaborations; Pfenex's expectations with respect to its agreements with Merck, SIIPL and Arcellx, including its potential to receive milestone and royalty payments; and Pfenex's beliefs with respect to its protein production platform and the quality of its development capabilities. Pfenex's expectations and beliefs regarding these matters may not materialize, and actual results in future periods are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Actual results may differ materially from those indicated by these forward-looking statements as a result of the uncertainties inherent in the clinical drug development process, including, without limitation, the FDA may not agree with Pfenex's protocol for a human factors study and may not grant an "A" therapeutic equivalence designation for PF708; Pfenex's ability to successfully demonstrate the efficacy and safety of its product candidates; the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates or may require Pfenex to conduct additional clinical trials or modify ongoing clinical trials or regulatory pathways; challenges related to commencement, patient enrollment, completion, and analysis of clinical trials; Pfenex's ability to manage operating expenses; impacts related to the COVID-19 pandemic; Pfenex's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives; Pfenex's dependence on third parties for development, manufacture, marketing, sales and distribution of products; unexpected expenditures; litigation and other proceedings regarding intellectual property rights; and difficulties in obtaining and maintaining intellectual property protection for its product candidates. Information on these and additional risks, uncertainties, and other information affecting Pfenex's business and operating results is contained in Pfenex's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 to be filed with the Securities and Exchange Commission and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Pfenex as of the date hereof, and Pfenex disclaims any obligation to update any forward-looking statements, except as required by law.

Company Contact:
InvestorRelations@pfenex.com

PFENEX INC.
Consolidated Statements of Operations
(unaudited)

(in thousands, except per share data)	Three Months Ended March 31, 2020	2019
Revenue		
License and service revenue	$ 301	$ 6,593
Product revenue	381	1,269
Total revenue	682	7,862
Cost of revenue		
License and service	242	903
Product	98	663
Total cost of revenue	340	1,566
Gross profit	342	6,296
Operating expense		
Research and development	5,811	7,880
Selling, general and administrative	4,732	4,543
Total operating expense	10,543	12,423
Net loss from operations	(10,201)	(6,127)
Other income, net	50	69
Net loss	$ (10,151)	$ (6,058)
Net loss per common share:		
Basic and diluted	$ (0.31)	$ (0.19)
Weighted-average common shares used in calculating net loss per share:		
Basic and diluted	33,151	31,487

PFENEX INC.
Consolidated Balance Sheets

	March 31, 2020 (unaudited)	December 31, 2019
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 65,602	$ 55,624
Restricted cash	200	200
Accounts and unbilled receivables, net	3,744	5,628
Other current assets	1,719	2,308
Total current assets	71,265	63,760
Property and equipment, net	8,465	7,744
Right-of-use asset	3,718	3,903
Other long-term assets	145	170
Intangible assets, net	3,607	3,733
Goodwill	5,577	5,577
Total assets	$ 92,777	$ 84,887
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 375	$ 673
Accrued liabilities	4,608	7,351
Current portion of deferred revenue	407	75
Lease liabilities – short-term	884	951
Other current liabilities	601	616
Total current liabilities	6,875	9,666
Lease Liabilities – long-term	2,699	2,896
Other non-current liabilities	28	26
Total liabilities	9,602	12,588
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value $0.001, 200,000,000 shares authorized; 34,265,401 and 32,266,708 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	35	33
Additional paid-in capital	291,033	270,008
Accumulated deficit	(207,893)	(197,742)
Total stockholders' equity	83,175	72,299
Total liabilities and stockholders' equity	$ 92,777	$ 84,887